K112509

NOV 4 2011

510(k) Summary of Safety and Effectiveness

TRIMED CLAVICLE FIXATION PLATES

Submitted/Distributed By:

TriMed, Inc.
27533 Avenue Hopkins
Santa Clarita, CA 91355
(800)633-7221

Registration No.:

2031009

Prepared By/Contact Person:

Doug Steinberger
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Proprietary Name:

TriMed Clavicle Fixation System

Classification:

Class II: Screw, Fixation, Bone
HWC – Section 888.3040
Class II: Plate, Fixation, Bone
HRS – Section 888.3030

Summary Preparation Date:

August 24, 2011

I. Indications for Use:

The TriMed Clavicle Fixation Plates and Screws are intended for use in fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle.

II. Device Description

The TriMed Clavicle Fixation Plates are designed to provide total immobilization of the clavicle. The plates utilize 2.7mm and 3.2mm locking and non-locking cortical screw to secure the plates to the bone. All plates and screws are similar to predicate devices. The TriMed Clavicle Fixation Plates are available in a variety of shapes and sizes to provide superior and anterior fixation of the clavicle.

III. Substantial Equivalence Discussion

When compared to the predicate devices listed below, substantial equivalence is based upon similarities in design features and overall indications for use.

510(k) Number	Device Name or System	Manufacturer
K100944	Clavicle Locking Plating System	NewClip
K012655	Congruent Bone Plate System	Acumed

An engineering analysis has been conducted to compare the bending strength of the TriMed Clavicle Fixation Plates to predicate devices to provide justification of the safety and effectiveness of the TriMed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV - 4 2011

TriMed Inc.
% Doug Steinberger
27533 Avenue Hopkins
Santa Clarita CA 91355

Re: K112509
Trade/Device Name: TriMed Clavicle Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 24th, 2011
Received: August 30th, 2011

Dear Mr. Steinberger:

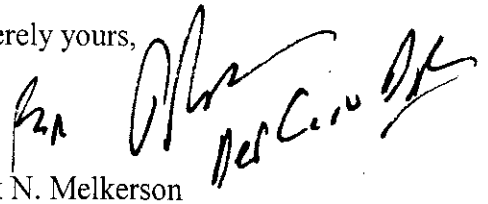
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): unknown K112509

Device Name: Clavicle Fixation System Plates and Screws

Indications For Use:

The Clavicle Fixation System Plates and Screws are intended for use in fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112509